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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,067

03/31/2005

Paola Ammannati

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10/18/2007

POLLACK, P.C.

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EXAMINER

HOBBS, LISA JOE

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,067

Applicant(s)

AMMANNATI ET AL.

Examiner

Lisa J. Hobbs

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-18, in the reply filed on July 30, 2007, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

The examiner notes the petition requesting withdrawal of the office action, filed concomitant with the response to the restriction requirement, and notes that the petition was dismissed in a decision dated September 19, 2007.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, establishing the instant case as the National Stage Application of PCT/IT02/00624, filed 10/01/2002, which papers have been placed of record in the file.

Claim Objections

Claim 6 is objected to because of the following informalities: "physiological solution" is misspelled at line 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 5-8 provide for the use of enzymes for the preparation of a pharmaceutical kit, but, since the claim does not set forth any steps involved in the method/process of preparing the kit, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 5-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process of preparing the instant pharmaceutical kit, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite that the enzymes are in about 0.4 ml of "physiological solution". There is no definition of "physiological solution" in the specification, although it is mentioned at pages 5 and 8. It is unclear if applicants mean some sort of standard saline solution or some other solution appropriate to the storage and use of these enzymes. As well, claims 3 and 7 recite the enzymes as being in "lyophilized form", but do not mention the presence of the "physiological solution" present in the independent claims, claims 1 and 5. It is unclear in these claims if there is no "physiological solution" provided, if it is provided separately in bulk, or if it is provided separately in aliquots for the purpose of effective reconstitution of the enzyme powders.

Claims 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 8 fail to further limit the kits of claims 1 and 5, which recite kits with enzymes in aliquot parts of "physiological solution". Although the claims recite the enzymes as being in "lyophilised form" in aliquot parts, it does not recite the "physiological solution" as being comprised in separate aliquot parts, thus the lyophilized enzymes could be present reconstituted in the "physiological solution", which is the same as the kit presentations in claims 1 and 5. As well, the amounts of "physiological solution" intended for each enzyme aliquot is unclear; if there is a range from 0.4 ml to 7.2 ml, the relationship between the amount of "physiological solution" and the amount of enzyme to be reconstituted, presuming that the concentration of the enzyme is important to the use of the kit is confusing.

Prior Art of Record

The examiner notes an international application filed by an inventor and the art cited by the EPO examiner for that application, Carmody et al. (1999) Reactive Oxygen Species as Mediators of Photoreceptor Apoptosis *in Vitro*. Experimental Cell Research 248(2): 520-530. As well, the examiner notes Ahuja-Jensen et al. (2007) Low glutathione peroxidase in rdl mouse retina increases oxidative stress and proteases. NeuroReport 18(8): 797-801.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Lisa J. Hobbs
Primary Examiner
Art Unit 1657

10/15/07

ljh